REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1, 3-22, 24-26 and 28-29 are in the present application. Independent claims 1 and 21 have been amended to specifically indicate that the controlled release coating of the claimed dosage forms comprises 45-80 weight percent of an enteric polymer. During preparation of this amendment Applicants noticed that the 45-80% enteric polymer limitation was present in claim 22 as originally filed but was not recited in the specification. Accordingly, Applicants have amended page 8 of the specification to include the 45-80% enteric polymer limitation in the specification. No new matter is added by the amendment to the specification or to claims 1 and 21. Support can be found in claim 22 as originally filed.

During preparation of this application, Applicants also noticed a typographical error in claim 22. Specifically, claim 22 recited a controlled release coating consisting essentially of 45-80% enteric polymer, 1-5%of a plasticizer and 20-60% of an anti-sticking agent. If 60% of the anti-sticking agent was employed and the minimum amounts of the other recited ingredients were employed, the total percentage would exceed 100%. In order to avoid this potential impossibility, Applicants have amended claim 22 by deleting the 20-60% requirement for the anti-sticking agent. In light of the amendment to claim 21 that limits the enteric polymer to 45-80% of the controlled release coating, a similar impossibility could have been present in claim 21. Accordingly, the 10-70% recitation of

anti-sticking agent has been deleted from claim 21. Both claims 21 and 22 still require the presence of an anti-sticking agent in the controlled release coating. No new matter is added by these amendments. Support can be found in claim 1, 9 and 15 as originally filed.

In the Office Action, on page 2, final paragraph, the Examiner rejected claims 1, 3-22, 24-26 and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Mehta et al. United States Patent No. 5,837,284 ("Mehta et al.") in view of Mulye, United States Patent No. 6,475,493 ("Mulye").

In response to this rejection, Applicants have amended the pending claims to require that the recited dosage form comprise a controlled release coating with 45-80% of an enteric polymer. As previously discussed no new matter is added by this amendment.

Applicants respectfully submit that the currently amended claims are patentable over the cited references either alone of combined because none of the cited references disclose or suggest to an individual of ordinary skill in the art an oral methylphenidate dosage formulation that employs 45-80% of an enteric material to aid in controlling the release of the methylphenidate.

As discussed in the prior Amendment, the Mehta reference discloses oral methylphenidate dosage forms that employ an immediate release dose and a controlled release dose, the Mehta reference fails to disclose or even remotely suggest the use of an enteric material to control the release of the methylphenidate. The Mehta reference only discloses the use of ammonio methacrylate copolymers to control the release of the methylphenidate. Col. 7, line 13-Col.8, line 57. Ammonio methacrylate copolymers are

not enteric materials.

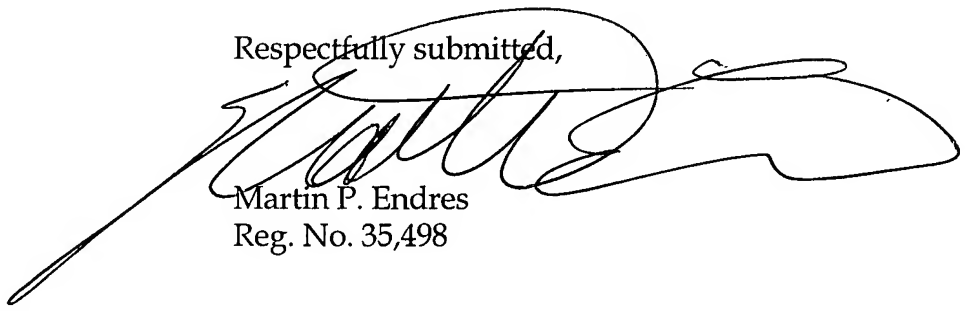
The Mulye reference teaches a controlled release dosage form, specifically a pellet, that is coated with a controlled release coating. The Mulye reference controlled release coating comprises at least 75% of a water insoluble polymer and 1-25% of an enteric polymer. Mulye, Col. 4, lines 30-49. The Mulye reference specifically teaches that the amount of enteric polymer should not exceed 25% of the coating. Mulye, Col. 6, lines 64-65 ("The enteric polymer, however, is preferably **not** present in amounts greater than 25% by weight of the coat." (emphasis added)). Clearly, the major and critical component of the controlled release coating taught by the Mulye reference is the water insoluble polymer with the enteric polymer present only in amounts less than 25%.

The Mulye reference also fails to provide any working examples that employ methylphenidate. The Mulye reference only discloses methylphenidate in a long list of potential drug candidates without any guidance of how to actual formulate methylphenidate. Mulye, Col. 9, line 5 to Col. 10, line 29.

It is respectfully submitted that the pending claims are patentable over the cited references either alone or combine because none of the cited references even remotely suggest preparing a methylphenidate dosage form comprising: (1) a methylpehindate core; (2) a controlled release coating applied to the core comprising 45-80% of an enteric polymer; and (3) an immediate release layer of methylphenidate applied to the controlled release core. In fact the Mulye reference specifically teaches away from a controlled release coating as recited in the pending claims.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,



Martin P. Endres
Reg. No. 35,498

MAILING ADDRESS:
HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036-2601
(212) 302-8989